BONE SUPPORT
injecting new strength

K073316

510(k) Summary

JUN 20 2008

Submitter Information

Manufacturer	BONESUPPORT AB Scheelevägen 19 A Ideon Science Park SE-223 70 LUND, SWEDEN
Telephone	+ 46 46 286 53 70
Company fax	+ 46 46 286 53 71
Contact person	Ann-Christine Provoost ann-christine.provoost@bonesupport.com + 46 46 286 53 22 (direct phone)

Date of preparation	10th of June, 2008

Trade name, Classification name, Class, Regulation

Trade Name	CERAMENT™|BONE VOID FILLER (A0210)
Classification Name	Resorbable calcium salt bone void filler device, MQV
Class	CLASS II (Special Control)
Regulation Number	CFR 888.3045

Predicate devices

510(k) number	*Trade name*	*Manufacturer*
K051951	CERAMENT™|BONE VOID FILLER (A 0066)	BONESUPPORT AB

Device description

CERAMENT™|BONE VOID FILLER is an injectable ceramic bone substitute material intended for bone voids. The material consists of a powder and a liquid component. The major constituents of the powder are calcium sulfate hemihydrate and sintered hydroxyapatite. The liquid component contains iohexol as a radio-opacity enhancer. Mixing the components, with the combined mixing injection device, results in a viscous material suitable for percutaneous

injection into a bone void. During resorption of the calcium sulfate dihydrate, the hydroxyapatite remains intact providing osteoconductive support for in-growth of new bone.

The ceramic bone substitute material is injected into the bone void in a percutaneous procedure, under visual inspection or under radiographic monitoring, with the use of the accompanying injection device.

Intended use

CERAMENT™|BONE VOID FILLER is a ceramic bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. CERAMENT™|BONE VOID FILLER is indicated to be injected into bony voids or gaps in the skeletal system, i.e. extremities, pelvis and spine (only during open surgery in spine). These defects may be surgically created osseous defects or osseous defects from traumatic injury to the bone.

CERAMENT™|BONE VOID FILLER provides a bone void filler that resorbs and is replaced by bone during the healing process.

CERAMENT™|BONE VOID FILLER is not intended for use in load bearing applications such as vertebroplasty or kyphoplasty.

Pre-clinical Testing

Extensive in vitro and in vivo testing has shown CERAMENT™|BONE VOID FILLER to meet the requirements of all relevant standards for Calcium Salt Bone Void Fillers. Extensive pre-clinical testing has confirmed CERAMENT™|BONE VOID FILLER to be safe and effective.

Summary

Based on the information provided in this premarket notification, the CERAMENT™|BONE VOID FILLER is equivalent to the predicate device in intended use, technological characteristics and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BONESUPPORT AB
% Ms. Ann-Christine Provoost
Contact Person Regulatory Affairs
Scheelevägen 19A
Ideon Science Park
SE-223 70 LUND, SWEDEN

JUN 20 2008

Re: K073316
Trade/Device Name: Cerament™ Bone Void Filler
Regulation Number: CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: April 17, 2008
Received: April 22, 2008

Dear Ms. Provoost:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073316

Device Name: CERAMENT™|BONE VOID FILLER (A0210)

Indications for Use:

CERAMENT™|BONE VOID FILLER is a ceramic bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. CERAMENT™|BONE VOID FILLER is indicated to be injected into bony voids or gaps in the skeletal system, i.e. extremities, pelvis and spine (only during open surgery in spine). These defects may be surgically created osseous defects or osseous defects from traumatic injury to the bone.

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Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073316